JUN 1 3 2001

510(k) Summary of Safety & Effectiveness

K011693

Submitter

Trumpf Medical Systems, Inc.
415 Jessen Lane
Wando, SC 29492

Contact

Mr. William Apperson
President and CEO
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Date

May 7, 2001

Device

- Trade Name: Trumpf Surgical Light
- Common Name: Surgical Light, Examination Light
- Classification: 21 CFR 878.4580 – Surgical Light – Class II
- Product Code FSY

Predicate Device

Drager Sola Surgical Light legally marketed under 510(k) premarket notification K984611.

Indications for Use

The Trumpf surgical lights are intended to locally illuminate an operating or examination area of the patient's body with high intensity light.

Device Description

Four models of the Trumpf surgical lights will be available: 301, 501, 701 and 1001. The versions differ in the diameter of the lamp housing (300 mm, 500 mm, 700 mm and 1000 mm, respectively). All lights are equipped with one or two halogen lamps and are available in either ceiling-mounted ("D") or wall-mounted ("W") configurations. The Model 301 is also available in a floor standing/mobile ("S") configuration. The lights may be mounted individually, but more typically are mounted as two- or three-unit aggregates.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Device Description, continued

An optional laser pilot is available on the Models 501, 701 and 1001. The laser pilot exactly marks the center of the light field. This makes it easier for the user to focus the light field with precision even if the operating area is very small. Whenever the operating light is moved/repositioned, the laser pilot is activated. When the operating light comes to a standstill, the laser pilot continues to be in operation for another two seconds. The laser pilot can be deactivated via the control panel. The laser wavelength is 635 nm with a nominal output power of < 1 mW.

The Model 1001 is also equipped with an anti-drift system. As soon as the light comes to a standstill, it will be fixed in position by built-in magnetic brakes. The brakes are automatically released whenever the handrail surrounding the light (or central handle) is touched.

Technological Characteristics

The technological characteristics of the Trumpf Surgical Light are the same as the predicate device, the Drager Sola Surgical Light. The physical characteristics, performance specifications, materials, dimensions and all other characteristics of the Trumpf surgical lights are identical to the Sola surgical lights.

Test Data

Test data to support the conformance to:

- IEC 60601-2-41 Standard – Particular Requirements for the safety of surgical luminaries and luminaries for diagnosis, First edition 2000-02
- IEC 601-1/EN 60601-1 Medical electronic equipment, Part 1, General requirements for safety,

and software testing demonstrates that the lights perform as intended and are safe and effective.

Conclusion

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Trumpf Surgical Light is substantially equivalent to the predicate device, the Drager Sola Surgical Light under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2001

Trumpf Medical Systems, Inc.
c/o Mr. Kent Donohue
Senior Staff Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle, North Carolina 27709

Re: K011693
Trade/Device Name: Trumpf Surgical Light Models 301, 501, 701 and 1001
Regulation Number: 878.4580
Regulatory Class: II
Product Code: FSY
Dated: May 30, 2001
Received: May 31, 2001

Dear Mr. Donohue:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K011693

Device Name: Trumpf Surgical Lights Models 301, 501, 701 and 1001

Indications for Use:

The Trumpf surgical lights are intended to locally illuminate an operating or examination area of the patient's body with high intensity light.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Miller
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011693